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**ABSTRACT:**

This invention is a needle assembly with a needle holder (1), a needle sleeve (2) movable over the needle holder, and an interlocking member (3) engaging the needle sleeve, and the needle holder. The needle sleeve encloses a needle holder, and is manually extendable and retractable in a telescopic manner to enclose or expose, respectively, the distal sharp portion of a needle without the aid of a spring or spring-like device. Temporary locking and release mechanisms in conjunction with the interlocking member control the position of the needle sleeve relative to the needle holder. The interlocking member clamps, snaps or slips into the needle holder, and engages with the needle sleeve. At the proximal end of the needle assembly is a connector for communicating the needle assembly to a hypodermic syringe or other fluid delivery device.



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<b>(21) International Application Number:</b> PCT/US97/14031 <b>(22) International Filing Date:</b> 8 August 1997 (08.08.97)  <b>(30) Priority Data:</b> 08/698,441           19 August 1996 (19.08.96)      US 08/896,277           7 July 1997 (07.07.97)         US  <b>(60) Parent Application or Grant</b> <b>(63) Related by Continuation</b> US                               08/896,277 (CON) Filed on                       7 July 1997 (07.07.97)  <b>(71)(72) Applicant and Inventor:</b> COSME, Edgar, Z. [US/US]; 1626 Peacock Lane, Fullerton, CA 92633 (US).  <b>(74) Agent:</b> SARNO, Maria, Erlinda, C.; P.O. Box 1023, Artesia, CA 90702 (US).		<b>(81) Designated States:</b> CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> NEEDLE ASSEMBLY  <div style="text-align: center;"> </div> <b>(57) Abstract</b> <p>This invention is a needle assembly with a needle holder (1), a needle sleeve (2) movable over the needle holder, and an interlocking member (3) engaging the needle sleeve, and the needle holder. The needle sleeve encloses a needle holder, and is manually extendable and retractable in a telescopic manner to enclose or expose, respectively, the distal sharp portion of a needle without the aid of a spring or spring-like device. Temporary locking and release mechanisms in conjunction with the interlocking member control the position of the needle sleeve relative to the needle holder. The interlocking member clamps, snaps or slips into the needle holder, and engages with the needle sleeve. At the proximal end of the needle assembly is a connector for communicating the needle assembly to a hypodermic syringe or other fluid delivery device.</p>		

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NEEDLE ASSEMBLYTechnical Field

The invention relates to a needle assembly with a sliding needle sleeve to shield the sharp distal end of a needle. This  
5 needle assembly, can be mounted on the forward end of a syringe body or other fluid delivery systems or reservoirs. A syringe utilizing this needle assembly offers protection to the user from unintended, accidental puncture.

Background

10 It is well known that used syringe needles may cause serious illness or untimely death if a person gets accidentally scratched by a needle previously used on an infected individual. Further, there has been a growing awareness of the danger of contracting AIDS, hepatitis or other known and unknown viral  
15 infections from accidental puncture with improperly discarded hypodermic needles.

The needle covers currently used in the medical field employ a conventional needle that is completely shielded by a removable plastic cover. The plastic cover is manually removed  
20 before an injection and manually recapped after use. For example, to recap after an injection, the user has to retrieve the needle from the patient before covering the needle with the plastic cover. Consequently, accidental puncture can occur while the user retrieves the needle from a patient before the  
25 needle can be covered for protection. Accidental removal of the plastic cover is also possible when a covered needle is discarded which can prick or scratch a user or bystander.

There has been a number of attempts to design a needle cover with varying degrees of success. Most of these devices known in the art basically consist of two cylindrical components, with one sliding over or inside the other in a telescopic manner aided by a spring mechanism for automatic shielding and exposure of the needle. These needle covers differ in their locking mechanism. These covers are either hard to assemble or expensive to manufacture due to the complexity of the mechanism.

It is an object of the present invention to provide a needle assembly which can protect the sharp tip of the needle from exposure prior to and during the mounting of the needle into the syringe body, between injections and after the needle has been discarded.

It is another object of the present invention to provide a needle assembly that is simple in design, easy and inexpensive to manufacture, that it can be offered as a disposable product.

#### Disclosure of Invention

The invention resides in a needle assembly that do not utilize a compressible spring device for covering or exposing the sharp distal tip of a needle by a sleeve. This needle assembly includes a needle holder, a needle sleeve and an interlocking member.

The needle holder is shaped like an open trough with a side extension. The trough can be cylindrical, ovoid or rectangular in shape. It has an open lateral distal end and a closed walled proximal end, a walled first and second longitudinal sides, a base and a hollow top surface. On the close walled proximal end

is a needle handle, preferably cylindrical in shape, protruding internally inwards of the needle holder, through which a metallic or a sharp polymeric needle is permanently attached. A pair of wing like structure preferably projects from the opposite lateral sides of the cylindrical needle handle to provide greater stability and firmness to the attached needle. Alternatively, the needle can be embedded on the upper portion of a solid base of the needle holder close to the hollow top surface. The proximal end of the needle, opposite the sharp distal tip is connected through the needle handle or through the solid base into a connector which extends beyond the closed walled proximal end of the needle holder. Instead of the connector directly attaching to the closed walled proximal end of the needle holder, the needle holder may have a recessed cylindrical extension between the closed walled proximal end and the connector to which an interlocking member can clamp or attach to. The distal end of the needle protrudes from the needle holder. A protrusion extends radially outward from the outer surface of the longitudinal walls at the distal end of the needle holder. In a cylindrical or similarly shaped needle holder, the protrusion extending radially outward is placed on one or both sides of the cylindrical body towards its distal end. As in the rectangular needle holder, the sides of the cylindrical body from which of these protrusions extend, will be likewise referred to as the longitudinal walls. The protrusion functions both as a stopping and an engagement device between the needle holder and a needle sleeve. The needle sleeve, over and around the needle holder, slides rearward or forward, along

the direction of the needle to shield or expose the needle. An interlocking member locks or release the telescopic motion of the needle sleeve relative to the needle holder. Telescopic motion means the needle sleeve can slide rearward or forward over the needle holder from a position wherein the needle sleeve completely envelopes the needle holder to a position where the needle sleeve extends outward away from the needle holder.

The needle assembly is commonly mounted to a hypodermic syringe but other fluid delivery devices may also be used with this assembly.

#### Brief Description of the Drawings

Figure 1 is a side view of a needle assembly showing the needle holder, the needle sleeve and the interlocking member slipped into the needle holder with the needle covered by the needle sleeve and a cap.

Figure 1A is a side view of another embodiment of the needle assembly showing the needle holder, the needle sleeve and the interlocking member clamped to a cylindrical extension on the needle holder having the needle covered by the needle sleeve and a cap.

Figure 2 is a perspective view of a rectangular needle holder showing the wing like structure projecting from the needle handle which is connected to a connector having a luer lock tip, the connector extending from the closed walled proximal end of the needle holder.

Figure 2A is a perspective view of a cylindrical needle holder having a recessed cylindrical extension to accommodate a clamping interlocking member.

Figure 2B is a perspective view of a rectangular needle holder showing the needle embedded on the upper portion of a solid base.

Figure 3 is a perspective view of one embodiment of an interlocking member.

Figure 3A is a perspective view of another embodiment of an interlocking member.

Figure 3B is a perspective view of another embodiment of an interlocking member.

Figure 4 is a perspective view of a rectangular needle sleeve.

Figure 4A is a perspective view of a cylindrical needle sleeve.

Figure 5 is a top view of the needle assembly having no cylindrical extension showing the protrusion engaged inside the groove with the needle shielded by the needle sleeve.

Figure 6 is a side view of the needle assembly with the needle exposed and the interlocking member clamped to the cylindrical extension of the needle holder.

Figure 7 is an exploded side view of the capping component.

#### Detailed Description of the Invention

The present invention resides in a needle assembly that do not utilize a compressible spring device for moving or locking a sleeve that covers the sharp distal tip of the needle. This needle assembly includes a needle holder 1, a needle sleeve 2 and an interlocking member 3 as shown in Figs.1 and 1A. The needle assembly is commonly mounted into a hypodermic syringe, preferably on a syringe body with a luer lock adapter or on



other fluid delivery source or reservoirs used and known in the medical field. In this invention, the distal end is the point away from the operator while the proximal end is the point close to the operator during the use of the device. The outer surface of the needle assembly can be rectangular, cylindrical, ovoid or  
5 similarly shaped but is preferably rectangular for ease of handling.

Examples of the needle holder are shown in Figs. 2, 2A and 2B. The needle holder 1 is shaped like an open trough with a  
10 horizontal extension. It has an open lateral distal end 4 and a closed walled proximal end 5, a walled first 6 and second 7 longitudinal sides, a base 8, a hollow top surface 9 and a protrusion 10. Descriptions for the cylindrical needle holder holds true for the ovoid or similarly shaped needle holder, the  
15 only difference between them would be on the contour of their outer surfaces, one would be circular or cylindrical while the other would be oval or ovoid in shape. For the cylindrical and similarly shaped needle holder, the parts corresponding but differentiated from the rectangular needle holder are generally  
20 identified with the same number but followed by the small letter a.

The needle holder may be solid, hollow interior, or a combination of both, made from materials such as glass, metal, hard rubber compound or plastic but is preferably made of  
25 plastic polymeric material such as polyvinyl chloride, polyvinylacetate, polyethylene, nylon, polyurethane, polypropylene, polycarbon, polyurethane, ethylene vinyl acetate, polysulfone, combinations of any of these formulations and the

like. Hard rubber compound means natural or synthetic rubber compounded with other fillers and agents to give the desired hardness to the resulting rubber material.

In the cylindrical design as shown in Fig. 2A, a hollow top opening 9a extends from the distal end 4a to the closed walled proximal end 5a. The sides along the length of the cylindrical, ovoid or similarly shaped needle holder is still referred to as the walled first and second longitudinal sides 6a or 7a even if one side is continuously connected to the other side, unlike in a rectangle where there is a distinct break between the longitudinal sides and the base. The protrusion 10a is placed at the distal end of either one or both of the longitudinal sides, 6a and 7a.

The protrusion 10 or 10a extends radially outward from the outer surface of the walls along the longitudinal sides 6 or 6a and 7 or 7a and is preferably slanted, with the thicker end towards the proximal end and is also preferably made of the same polymeric material as the body of the needle holder. The protrusion 10 or 10a functions both as a stopping device and an engagement device between the needle sleeve and the needle holder.

In the rectangular design as shown in Figs. 2 and 2B, the walls along the longitudinal sides 6 and 7 have an overhang 11 bordering the entire length of the longitudinal walls which extends internally, that is, inwardly towards the interior of the needle holder. For the cylindrical design, the curvature 21 bordering the hollow top surface or opening 9a functions as the

overhang 11. The wall that laterally borders the closed wall proximal end 5 or 5b may extend slightly pass the longitudinal walls 6 or 6a and 7 or 7a to cause a protruding fence 12 which can be either on one side or on both sides of the closed wall proximal end 5 or 5b as shown in Figs. 2, 2A and 2B. The needle can attach to the needle holder in different ways. An example is shown in Figs. 2 and 2A wherein midway from the inner wall 13 of the closed proximal end 5 or 5a, there is a needle handle for holding the needle. The needle handle is a solid protruding body 14, preferably cylindrical in shape through which a sharp metallic or hard polymeric needle 15 is permanently attached. The needle handle 14 may have a pair of horizontally oriented wing-like structure 16 projecting from the opposite lateral sides of the needle handle to provide greater firmness and stability to the needle. The wing-like projections 16 preferably extends to the inner walls 17 or 17a of the longitudinal walls 6 or 6a and 7 or 7a as shown in Figs. 2 and 2A. Another example of needle attachment is shown in Fig. 2B. Here, the needle is attached by embedding the needle in the base of the needle holder, which is preferably solid and thicker to accommodate the needle. The distal end of the needle protrudes from the needle holder 1. The needle has a hollow interior, lumen 18, and could vary in sizes and gauges. The proximal end of the needle is connected to a two ended connector 19. The connector is preferably made of the same polymeric material as the needle holder. The connector 19 has a hollow preferably conical interior, a cone tapered shaped cavity, converging at

one end with the proximal end of the hollow needle 15 so as to communicate with the lumen 18 of the needle, through which materials, preferably liquids or suspensions, may be introduced. The other end of the connector, one not connected to the needle, preferably has a luer lock tip 20. The connector 19 is the horizontal extension of the needle holder 1. The distal end of the connector may connect to the proximal end of the needle from the closed walled proximal end 5 or it may connect inwards of the closed walled proximal end so as to be partly into the interior of the needle holder.

The needle holders shown in Figs. 2 and 2B do not have a recessed cylindrical extension 31 between the closed walled proximal end 5 or 5a and a second 5b closed walled proximal end as shown in Fig. 2A and a cut out area 32 from the top of the closed walled proximal end 5 or 5a of the needle holder 1 for accommodating an interlocking member 3 that clamps rather than slips into the needle holder as shown in Fig. 1A. The width of the recessed cylindrical extension 31 of the needle holder 1 varies, it may be as narrow as a wire if for example, the clamping means of the interlocking member is shaped like a ring or it may be wider to match the width of the clamping means. The depth of the recessed cylindrical extension 31 matches the thickness of the clamping means of the interlocking member 3 while the depth of the cut out area 32 on the top of the closed walled proximal end 5 matches the thickness of the interlocking member 3 such that the outer walls of the needle holder, the interlocking member when pressed into the hollow top surface 9

and that of the connector 19, preferably align when the interlocking member 3 is clamped into the needle holder 1.

Although a cylindrical needle holder with a recessed cylindrical extension is shown in Fig. 2A, the needle holder with a recessed  
5 cylindrical extension can also be rectangular, ovoid or similarly shaped.

The interlocking member which controls the position of the needle sleeve in relation to the needle holder, depending on its design, can either snap, slip or clamp into the needle holder.

10 The interlocking member 3 as shown in Fig. 3 slips into the hollow surface 9 of the needle holder 1 and is held inside the hollow top surface of the needle holder by the overhang 11 along the longitudinal walls 6 and 7 of the rectangular needle holder or by the curvature 21 for the cylindrical, ovoid or similarly  
15 shaped needle holder. The proximal end 22 of the interlocking member 3 is preferably planar for the rectangular needle holder. Connected along the longitudinal edges 23 at the proximal end of the interlocking member is a downward step-legged projection 24 that stands on the base 8 of the needle holder 1 to support the  
20 interlocking member 3. For needle holders with wing-like projections 16, the step-legged projection 24 can be shorter because it can stand on top of the wing-like projection 16 rather than extending all the way to the base 8 of the needle holder. The step-legged projection fits underneath the overhang  
25 11. The step portion 25 of the step-legged projection 24 and the overhang 11 are shaped to match each other and are of the same dimensions to allow a good fit. The interlocking member 3

as shown in Fig. 3A can slip or snap into the hollow top surface 9 of the needle holder. The design is similar to that shown in Fig. 3 except that the latter is thicker and the corresponding proximal planar portion 22' occupies the hollow top surface 9 when inserted into the needle holder. The planar portion 22' has a recess 25' along a proximal portion of its longitudinal edges, which corresponds to the step portion 25 of the interlocking member shown in Fig.3. The recess 25', like the step portion 25, is shaped to match the dimensions of the overhang 11. For cylindrical, ovoid, or similarly shaped needle holders, the entire outer surface of the interlocking member is preferably curved in such a direction that when the interlocking member slips into the curvature 21, the interlocking member covers the top opening or top surface 9a of the needle holder to result in a cylindrically shaped outer surface. The distal end of the interlocking member 3 shown in Figs. 3 and 3A preferably extends upward at an angle and is referred to as angular end 26. The angular end 26 may have a width narrower than the planar end and is of such width that its longitudinal edges 23 just freely rub on the longitudinal inside tip 27 of the needle holder 1, allowing unimpeded up and down motion of the angular end 26. At the distal portion of the angular end 26 is a stepped recess which look like a fore and middle finger projection, hence will be referred to as finger hook 28. The finger hook has a notch 29. Before the finger hook 28, for the planar interlocking member, there is preferably, a slightly elevated hump 30 to allow a tighter engagement between the interlocking member 3 and

the needle sleeve 2 as shown in Fig. 3.

The interlocking member 3 as shown in Fig. 3B clamps or snaps into the outer surface of the recessed cylindrical extension 31 shown in Fig. 2B of the needle holder as shown in Figs. 1A and 2B. At the proximal end of the interlocking member 3 is a clamp 33 shaped like a letter "C" facing downwards as shown in Fig. 3B and hence will be referred to as the C-clamp 33. For the rectangular needle holder, the interlocking member 3 is planar or flat. In the cylindrical, ovoid or similarly shaped needle holder, the interlocking member is preferably curved such that when the interlocking member 3 is clamped to the needle holder, positioned over the cut out area 32, the interlocking member 3 covers the top opening of the needle holder as shown in Fig. 1A to result into a cylindrical outer surface. This interlocking member 3 also preferably extends upwardly at an angle. The distal angular end 34 is referred to as angular end 34 and the proximal end connected to the C-clamp 33 is referred to as proximal end 35. The angular end 34 preferably has the same width as the proximal end 35. Like the other interlocking member 3, it is of such width that its longitudinal edges 39 just freely rub on the longitudinal inside tip of the needle holder 27 or 27a, allowing unimpeded up and down motion of the interlocking member. The distal portion of the angular end 34 also ends with a finger hook 36, the stepped recess which look like a fore and middle finger projection. The finger hook has a notch 37. Before the finger hook 36, for the planar interlocking member, there is preferably, a slightly

elevated hump 38 to allow a tighter engagement between the interlocking member 3 and the needle sleeve 2.

The interlocking member 3, as the needle holder 1, may be made of solid material or it may have a hollow interior. It can be made of metal, hard rubber compound, but is preferably made of the same preferred polymeric material used for the needle holder 1 but is of a kind that is non-brittle, durable and resilient with memory. With memory means the material will return to its original configuration when the restraining means which keeps the material stationary at a strained position, is released.

The needle sleeve 2 is shaped to conform with the outer contour and surface of the needle holder 1. For ease of handling, the needle sleeve is preferably shaped like a hollow rectangular box, as shown in Fig. 4 or a hollow cylindrical or ovoid tube for the cylindrical or ovoid needle holder as shown in Fig. 4A. The needle sleeve has an open proximal 40 and distal 41 lateral ends to allow the needle sleeve 2 to slide over the needle holder 1 in a telescopic manner relative to the needle holder. The closed sides of the rectangular needle sleeve are the longitudinal side walls 42 and 43 and the top and bottom surfaces 44 and 45. The top surface 44 of the rectangular needle sleeve has a cutout area 46 on the proximal end 40, preferably rectangular in shape as shown in Fig. 4. The cutout area has three sides, two horizontal sides 47 and 48 and a frontal side 49. All three sides may be blunt ended but it is preferable for the frontal side 49 to have a slant edge as shown



in Figs. 1 and 4. The cut out area leaves a horizontal overhang 50. For the rectangular needle sleeve, the overhang 50 rests over the overhang 11 of the needle holder 1. The overhang 11 functions like a track over which the sleeve traverses to and from.

For the cylindrical, ovoid or similarly shaped needle sleeve as shown in Fig. 4A, the cut out area 46a from the proximal end 40a of the needle sleeve is also preferably rectangular in shape and is preferably of the same width as the hollow top surface opening 9a of the needle holder. A curved surface 52 is left after cutting out area 46a which functions like the overhang 50 and rests over the curvature 21 on the main body of the needle holder. The curvature 21 functions as a tract through which the needle sleeve traverses to and from.

For the cylindrical or other similarly shaped design such as an ovoid, the only difference from that of the rectangular shaped needle sleeve is the absence of corners to distinguish the sides, that is, there is no distinct break differentiating one side from the other.

At a calculated or measured distance, starting approximately a third of the full length of the needle sleeve 2 from the proximal end 40 or 40a, are grooves 51 along the inner surface of the longitudinal walls 42 or 42a and 43 or 43a as shown in Figs. 4 and 4A. These grooves engage with the protrusion 10 or 10a and function as a track (shown in Fig. 4 as broken line) through which the protrusion 10 or 10a can traverse to and from horizontally as shown in Fig. 5. The outer surface

of the longitudinal walls 42 or 42a and 43 or 43a of the needle sleeve may be smooth or gridded. However, it is preferable to grid the outer sides of the walls to provide a better grip for the user. The needle sleeve, as the needle holder, can also be  
5 made of metal, glass, hard rubber compound or plastic polymeric material but is preferably made of the same polymeric material as those used for the needle holder and interlocking member.

When the sliding needle sleeve 2 is slid over the top surface of the needle holder 1 from a position covering the  
10 needle holder as shown in Fig. 6, to a direction towards the tip of the needle 15, the leafspring action of the angular end 26 or 34 allows the finger hook 28 or 36 to rest on the inside wall of the top surface 44 or 44a of the sliding needle sleeve and the notch 29 or 37 to rest on its frontal side 49 as shown in Fig.

1. At this position, the entire needle is shielded and the sleeve is temporarily locked. Leafspring effect is the counter effect produced when the upward angular distal 26 or 34 end of the interlocking member is pressed downward while the proximal end 22 or 35 is kept stationary in one position. The needle  
15 assembly with the needle sleeve 2 in this forward position, shielding the needle 15, is temporarily locked in this position by the finger hook 28 or 36 abutting on the frontal side 49 of the cutout area afforded by its leafspring effect. The finger hook 28 or 36 protrudes over the top surface 44 thereby  
20 preventing the needle sleeve 2 from moving away from the direction of the needle, as shown in Fig. 1. On the other hand, the forward motion of the needle sleeve 2 towards the direction  
25

of the needle is checked when the protrusion 10 or 10a abuts at the end 53 of the grooves 51 as shown in Fig. 5. The grooves 51 prevent the needle sleeve 2 from disengaging with the protrusion 10 or 10a of the needle holder.

5           The procedure for exposing the distal tip of the needle 15 from a position where the needle sleeve 2 shields the entire needle body is accomplished by pressing on the top surface of the finger hook 28 or 36 downward or if there is a hump 30 or 38, on the hump, towards the hollow top surface 9 or 9a of the  
10 needle holder, to release its engagement from the frontal side 49. Once the finger hook 28 or 36 no longer abuts on the frontal side 49, the needle sleeve can be manually moved rearward or slid rearward in a direction away from the needle, thereby exposing its distal end as shown in Fig. 6. At this  
15 position, the needle is free for usage for any purpose such as injection, infusion, pricking and the like. The needle sleeve 2 is collectively kept from moving forward or rearward during its use by the slightly flaired edge 54 shown in Fig. 5 at the outside junction between the longitudinal walls 6 and 7 and the  
20 fence 12, and the hump 30 or 38 touching on the inner surface 55 of the needle sleeve, providing resistance to unassisted movement. Further, since the inside surface dimensions of the needle sleeve is barely larger than the outer surface dimensions of the needle holder, only enough to allow it to slide over the  
25 needle holder, additional frictional resistance is provided. The protruding fence 12 on one or both sides of the closed walled proximal end 5 or 5b of the needle holder also stops any

further rearward motion of the needle sleeve 2. After use, the needle sleeve 2 is merely pushed forward to a position wherein the finger hook 28 or 36 reengages automatically with the frontal side 49 because of the angular design and leafspring effect of the distal portion of the interlock member. This process allows one to manually slide with ease, the needle sleeve 2, forward and rearward in relation to the needle holder 1, to cover and uncover the sharp distal end of the needle 15 without the use of a spring device and complex mechanisms.

For packaging, shipping or when discarding the needle assembly after use, it is preferable to incorporate a capping component 56 for covering the distal and the proximal end of the needle assembly to further prevent accidental puncture or scratching with the tip of the needle. The cap can be made of metal, glass or hard rubber compound but is preferably made the same polymeric material as those used for the other components of the needle assembly. As shown in Figs. 1 and 1A, it is sufficient to have only one cap covering the open distal end of the needle assembly if the entire assembly, for example, will be packaged inside a pouch or container. If only one cap is used, the cap 56 extends preferably from the distal tip of the needle sleeve to a position in front of the finger hook 28 or 36 which protrudes over the needle sleeve 2 when the needle assembly is stored or discarded as shown in Figs. 1 and 1A. The inner wall of the cap 56 is preferably thicker at its distal end than at its proximal end to cause the cap to receive and fit snugly into the needle assembly thereby preventing the cap 56 from

unassisted slippage as shown in Fig. 7.

Due to the simplicity in design of the needle assembly and the availability of needles and suitable plastic materials at rather reasonable prices, this device can be made available as a  
5 disposable product for one time or limited time usage.

While the embodiments of the present invention have been described, it should be understood that various changes, adaptations, and modifications may be made therein without departing from the spirit of the invention and the scope of the  
10 claims.

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What is claimed is:

1. A needle assembly for use with a fluid delivery device, comprising:

5 a needle holder having a closed walled proximal end, an open distal end, a walled first and second longitudinal side, a base, a hollow top surface, a hollow needle, means for attaching the needle, and a two ended hollow connector mounted to the hollow needle at one end;

10 a sliding needle sleeve for surrounding the needle holder, the sleeve slidably movable relative to the needle holder in the direction of the length of the needle from a first position in which the needle projects outside of the needle sleeve to a second position in which the needle is within the needle sleeve;

15 means for engaging the needle holder with the needle sleeve;

means for interlocking the needle sleeve with the needle holder; and,

20 means for stopping the rearward and forward motion of the needle sleeve relative to the needle holder.

2. The needle assembly of claim 1 wherein the first and second longitudinal walls of the needle holder have overhangs bordering the entire length of the walls and directed inwards for receiving the interlocking means.

25 3. The needle assembly of claim 1 wherein the hollow needle has a lumen in direct communication with the hollow connector, the hollow connector having a cavity tapering into the lumen of the needle.

4. The needle assembly of claim 1 wherein the other end of the hollow connector not connected to the needle has a luer lock tip.

5. The needle assembly of claim 1 wherein the means for attaching the needle is a solid protruding body from the inner wall of the closed walled proximal end of the needle holder.

6. The needle assembly of claim 1 wherein the means for attaching the needle is by embedding the needle in the base of the needle holder.

10 7. The needle assembly of claim 1 wherein the needle sleeve has a gridded area on the outer surface.

8. The needle assembly of claim 1 further comprising of a cap means for closing an end of the needle assembly.

15 9. The needle assembly of claim 1 wherein the means for interlocking the needle sleeve with the needle holder is an interlocking member comprising a proximal end, an angular distal end, a downward step-legged projection on the proximal end, and a finger hook on the distal angular end for engagement and release.

20 10. The needle assembly of claim 1 wherein the means for interlocking the needle sleeve with the needle holder is an interlocking member comprising a proximal end, an angular distal end, a recess on the longitudinal sides of the proximal end, and a finger hook on the distal angular end for engagement and  
25 release.

11. The needle assembly of claim 1 wherein the needle assembly is disposable.

12. The needle assembly of claim 1 further comprising a

second closed walled proximal end, a recessed cylindrical extension between the closed walled proximal end and the second closed walled proximal end, and a cut out area from the top of the closed walled proximal end.

5           13. The needle assembly of claim 12 wherein the needle assembly is made of material selected from the group consisting of glass, metal, hard rubber compound and plastic polymeric material.

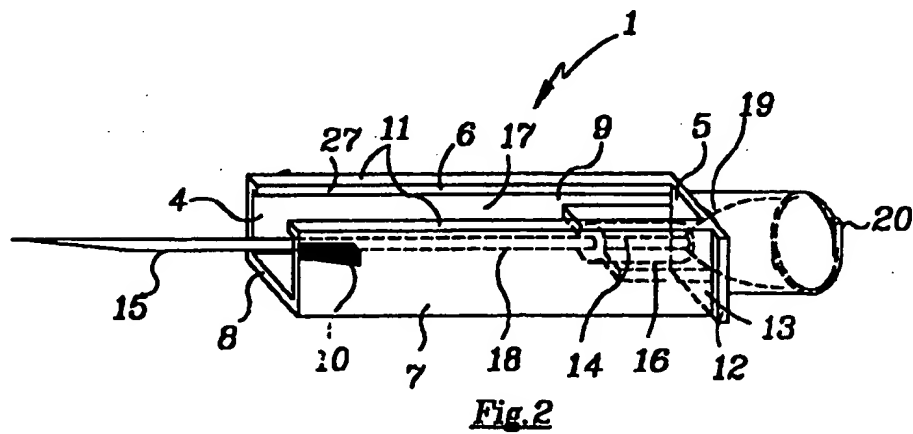
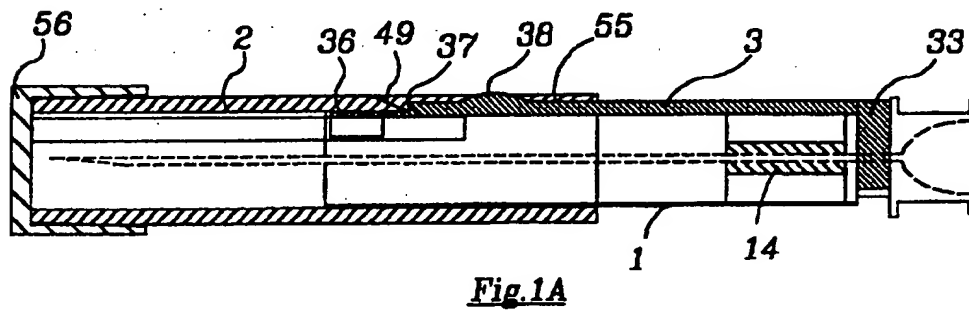
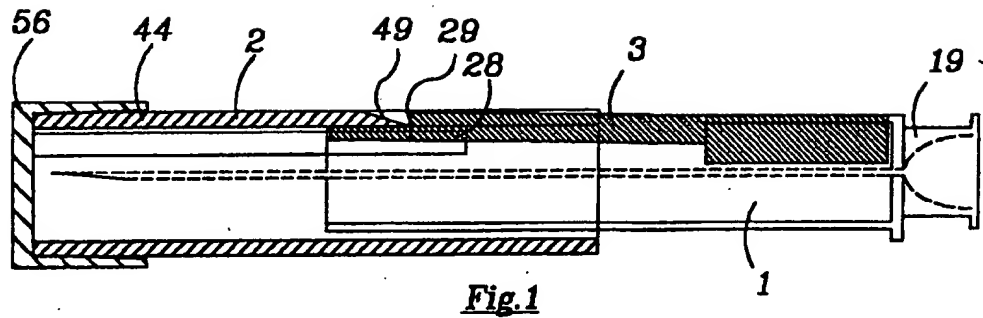
10           14. The needle assembly of claim 13 wherein the polymeric material is selected from the group consisting of polyvinyl chloride, polyvinylacetate, polyethylene, polypropylene, nylon, polycarbon, polyurethane, ethylene vinyl acetate, polysulfone and combinations of any of these formulations.

15           15. The needle assembly of claim 12 wherein the hollow needle has a lumen in direct communication with the hollow connector having a cavity tapering into the lumen of the needle.

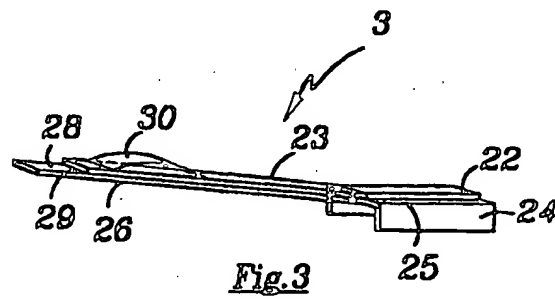
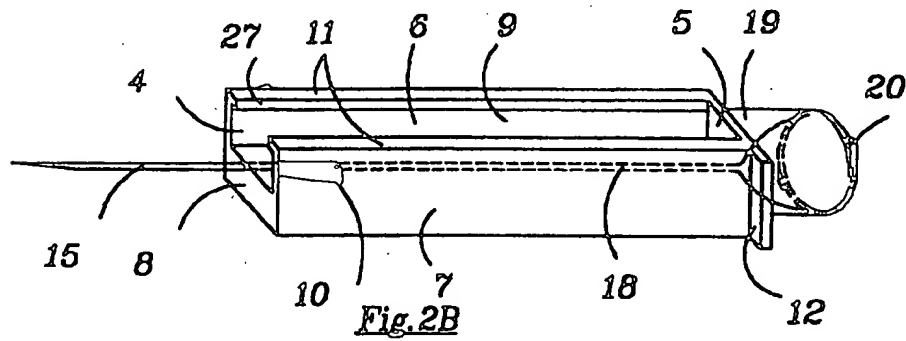
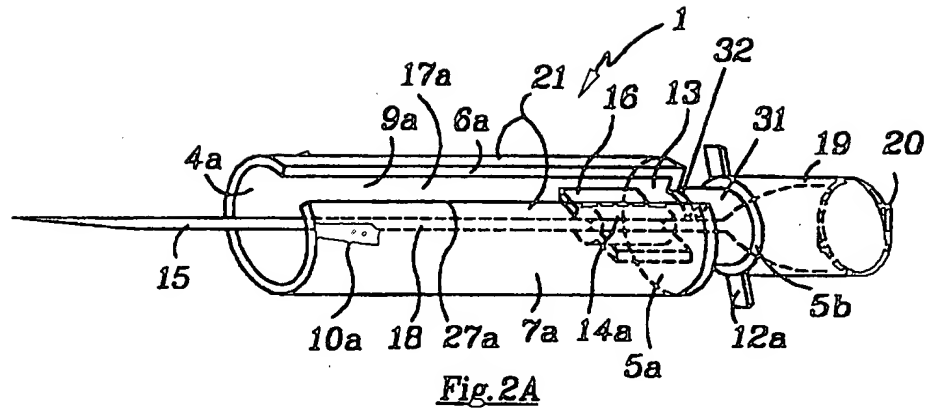
20           16. The needle assembly of claim 12 wherein the means for interlocking the needle sleeve with the needle holder is an interlocking member comprising a proximal end, an angular distal end, a clamp on the proximal end, and a finger hook on the distal angular end for engagement and release.

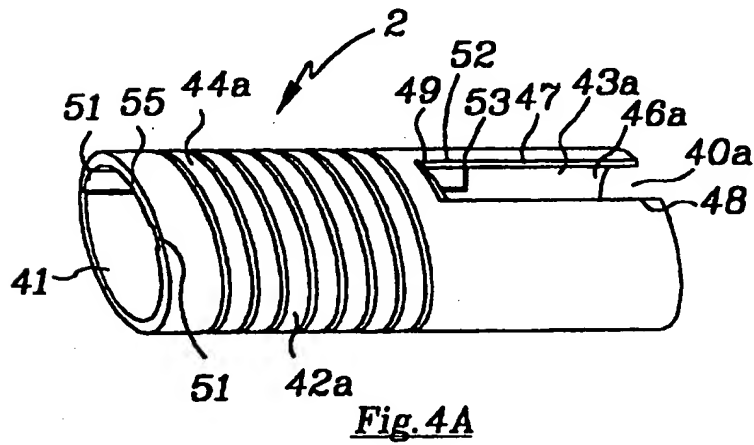
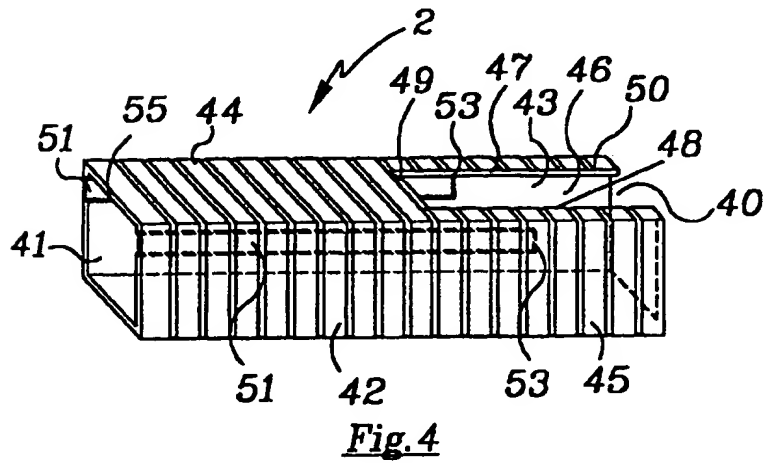
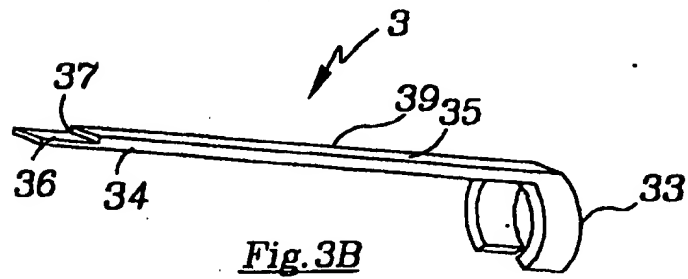
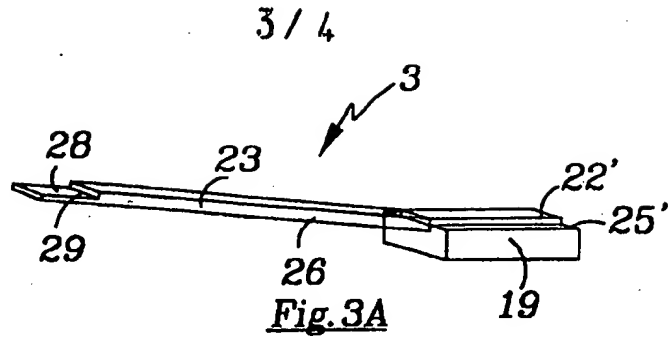


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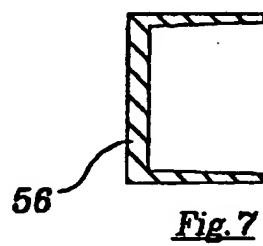
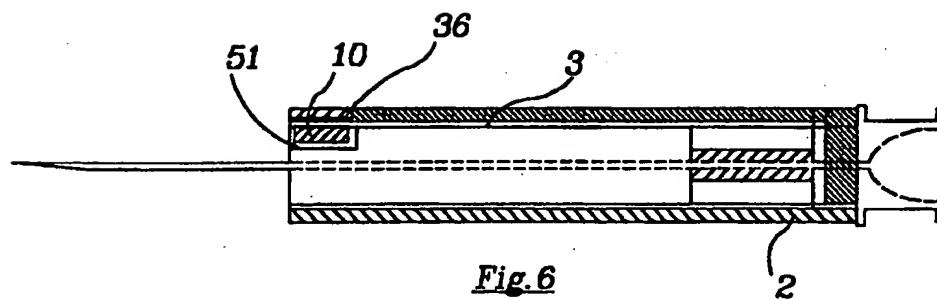
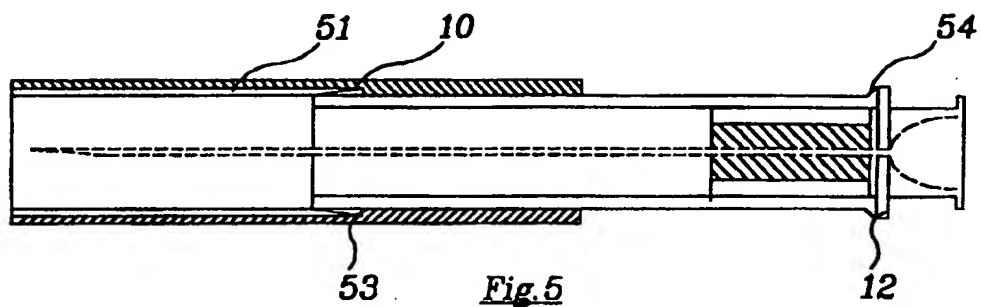


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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/14031

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/32

US CL :604/192

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/187, 195, 198, 263, 272

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,108,378 A (FIRTH et al) 28 April 1992, entire document.	1-16
A	US 1,921,034 A (LA MARCHE) 08 August 1933, entire document.	1-16



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	* T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* A* document defining the general state of the art which is not considered to be of particular relevance	* X	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* E* earlier document published on or after the international filing date	* Y	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* A*	document member of the same patent family
* O* document referring to an oral disclosure, use, exhibition or other means		
* P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

03 OCTOBER 1997

Date of mailing of the international search report

22 DEC 1997

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